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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,987	10/31/2006	James Carlyon	1502-84PCTUSCIP	8863
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Tyco Healthcare Group LP				
d/b/a Covidien				
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Mansfield, MA 02048				
EXAMINER				
PRICE, NATHAN R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/585,987

Applicant(s)

CARLYON ET AL.

Examiner

NATHAN R. PRICE

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on February 27, 2009. As directed by the amendment: claims 1, 15, 20, 26, 27, and 40 been amended, no claims have been cancelled, and no new claims have been added. Thus, 1-40 are presently pending in this application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 7226434.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the current claims are present in the claims of the patent.

Terminal Disclaimer

4. Examiner acknowledges Applicant's statement on page 14 of the Remarks regarding intent to file a Terminal Disclaimer if the claims are indicated otherwise allowable. The Double Patenting rejection is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Woehr et al. (US 6287278). Woehr et al. discloses a safety shield (fig. 4A-B) comprising: a

piercing member 16 (fig. 4A-B) having a distal end and defining a longitudinal axis (see fig. 4A-B); a clip 40a (fig. 4A-B) defining a first cavity 84 (fig. 4A-B, which includes a slot) dimensioned for movement of the piercing member therethrough (from fig. 4A to 4B) and being oriented in an axis transverse to the longitudinal axis of the piercing member (see fig. 4A-B), the clip being moveable from a first orientation to a second orientation to reposition the first cavity from a moveable orientation to a binding orientation (from fig. 4A to fig. 4B); the clip including a first leg (extending between 72 and 66, fig. 4A-B) that defines a second cavity 70 (fig. 4A-B) dimensioned for movement of the piercing member therethrough and a distal part 67 (fig. 4A-B) being configured to engage a medical device when the clip is in the first orientation (see fig. 4A; engages medical device via engagement with 68), the clip further including a second leg 74 (fig. 4A-B) having a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation (interior of aperture 76; fig. 4A-B); wherein the first leg and the second leg are biased for convergent movement such that when the piercing member is withdrawn from the second cavity, the clip moves from the first orientation (fig. 4A) to the second orientation (fig. 4B) to move the first cavity from the moveable orientation to the binding orientation (from fig. 4A to 4B), wherein the distal part of the first leg disengages from the medical device when the clip is in the second orientation (67 disengages from 68, fig. 4A-B); the first cavity is rotatable relative to the longitudinal axis of the piercing member (entire clip could be rotated around the longitudinal axis, fig. 4A-B); the first cavity defines a binding surface that engages the piercing member in the binding orientation (interior of aperture 84); a plate

82 (fig. 4A-B) that defines the first cavity and is oriented substantially perpendicular to the legs; the first leg has a proximal part that is oriented substantially perpendicular to the transverse axis of the first cavity in the moveable orientation (area between 72 and 70, fig. 4A-B); the second leg has a proximal part 78 (fig. 4A-B) that is oriented substantially perpendicular to the transverse axis of the first cavity in the moveable orientation (fig. 4A-B); the distal part of the first leg includes a transverse portion that defines the second cavity (see fig. 4A-B); the distal part of the first leg includes an arm 67 (fig. 4A-B) configured to releasably retain the medical device; the clip is disposed within a housing (defined by 32 and 12, fig. 4A); the housing is moveable between a retracted position whereby the distal end of the piercing member is exposed and an extended position whereby the housing encloses the distal end of the piercing member (from fig. 4A to fig. 4B, shown removed in fig. 4B, but prior to removal, housing would enclose the distal end of the piercing member); the clip releasably retains the medical device (the catheter through which piercing member extends, fig. 4A) with the housing (by retaining the housing via nub 68, fig. 4A); the housing includes a flash chamber (interior of 12, fig. 4A-B); a transition portion (defining 80; fig. 4A-B) that connects the plate with the first leg and configured to engage an inner surface of the housing (via engagement to 67, fig. 4A-B).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whoer et al. Woehr et al. discloses, in fig. 4A-B, the apparatus as claimed except for a network of biasing elements configured to bias the clip defining channels therebetween and connected to form a continuous spring. However, in fig. 12, Woehr et al. teaches a clip comprising a network of biasing elements 160 and 162 defining channels therebetween and continuously formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus of fig. 1a and 1b such that a network of biasing elements is configured to bias the clip defining channels therebetween and connected to form a continuous spring, as taught by fig. 12, for the purpose of providing sufficient biasing force to increase the security of the piercing element within the safety shield.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art
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